DRUG ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN USED ACCORDING TO DIRECTIONS

4381. Action to enjoin and restrain violations of Sections 301 (a) and 301 (k) with respect to Nu Youth tablets. U. S. v. Frederic S. Weichman, alias Fred Weichman, F. Weichman, and Fred Whiteman (N-Y Distributing Co.). Consent decree of injunction granted. (Inj. No. 277.)

COMPLAINT FILED: March 10, 1954, against Frederic S. Weichman, alias Fred Weichman, F. Weichman, and Fred Whiteman, doing business under the name of the N-Y Distributing Co., Hollywood, Calif.

NATURE OF CHARGE: The complaint alleged that the defendant was engaged in the interstate business of distributing and selling a drug consisting of 5 milligram methylandrostenediol tablets, designated by the name "Nu Youth"; that the methylandrostenediol contained in the Nu Youth tablets was believed to have been received in interstate commerce in the State of California, and that thereafter the defendant caused certain printed matter, including the label on the bottles containing the drug, a form letter addressed to "My Dear Friend," and a folder entitled "The Evidence," to become the labeling of the drug while held for sale after shipment in interstate commerce.

The complaint alleged further that the defendant was violating Section 301 (k) of the Act by causing the Nu Youth tablets to become misbranded while held for sale after shipment in interstate commerce, and that he also was violating Section 301 (a) of the Act by causing the introduction and delivery for introduction into interstate commerce of the misbranded Nu Youth tablets.

The Nu Youth tablets were alleged to be misbranded as follows:

Section 502 (a), the labeling of the tablets was false and misleading since it represented, suggested, and created the impression in the mind of the prospective purchaser to whom it was directed:

- (a) That the tablets were an adequate and effective treatment for providing in men over 40 renewed vigor, endurance, strength, and vitality; for rejuvenating men by replenishing their deficient sex glands; for restoring masculine sex drive; for banishing mental fatigue, boosting muscle power, replenishing energy and endurance, increasing mental alertness, and ending irritability; for providing health, sexual aliveness, and emotional stability; for sex problems and impotency; for restoring waning physical and mental powers in men; for providing pep and vitality; and for providing proper functioning and well-being for the human body, whereas the tablets were not an adequate and effective treatment for such purposes and conditions;
- (b) That the tablets may be used in place of the drugs, testosterone, methyltestosterone, and testosterone proprionate, for their androgenic effect, whereas the tablets possessed far less androgenic activity than those drugs;
- (c) That each of the tablets was a natural, safe, needed, true, and normal male sex hormone, whereas each tablet was not a true or normal male sex hormone, nor was it a naturally occurring product, nor was it safe for use except under medical supervision, nor was it needed in normal body function; and,
- (d) That each tablet was an anabolic agent, whereas the labeling failed to reveal the material fact in the light of such representation that